

NIH Roadmap for Medical Research

**Institutional Clinical and Translational
Science Awards (CTSA)**

Building an Academic Home

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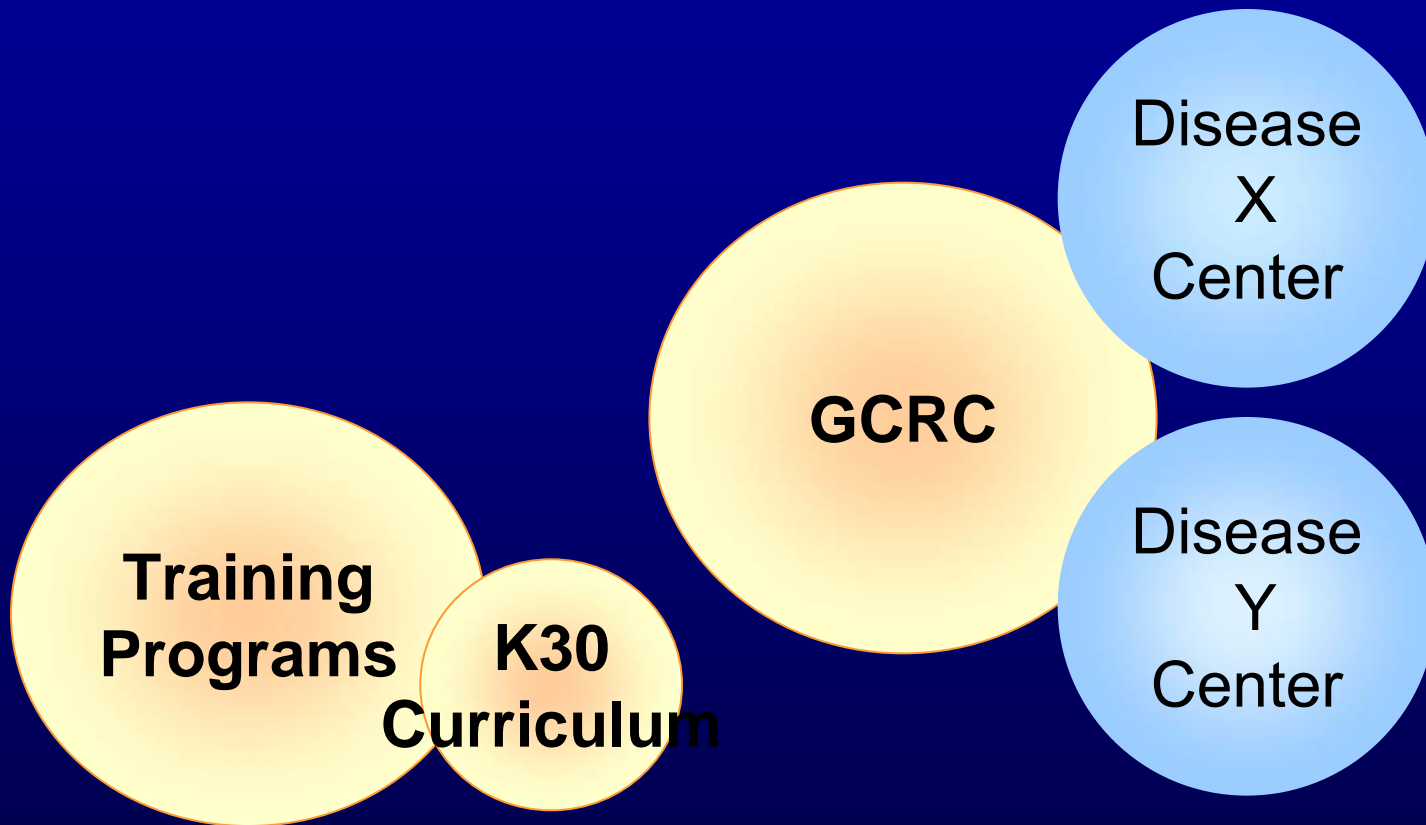
A Transforming Approach: NIH Institutional Clinical and Translational Science Awards (CTSA)



- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science
- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly
- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems
- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions



Where are we starting from?

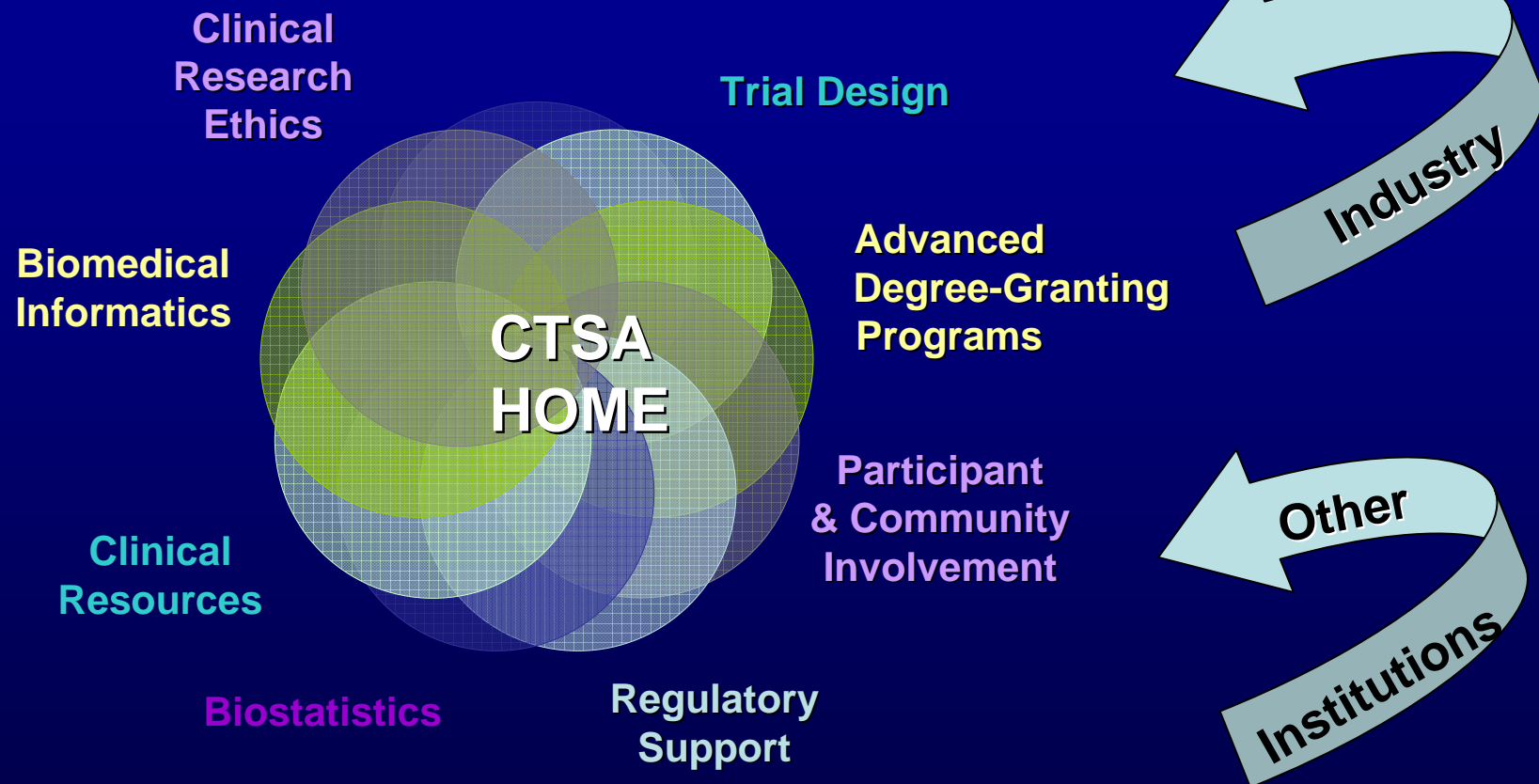


How is this transformation achieved?

- Through the NIH Roadmap for Medical Research, create an integrated environment for the clinical and translational researcher that can provide:
 - an academic home for clinical research (a Center, Department, or Institute [C/D/I])
 - support for protocol preparation, regulatory compliance and data management
 - support for participant recruitment, human subject safety monitoring
 - education leading to advanced degrees in clinical research
 - specialized cores and services for translational research



NIH CTSA Awards: A Home for Clinical and Translational Science



Definitions

Clinical Research covers all studies of diseases and trials of treatments that take place in human subjects

Translational Research describes the steps between a fundamental discovery and its application in clinical medicine. For example:

- 1) Testing a new anti-cancer drug in humans for the first time**
- 2) Identifying best practices in the diagnosis, prevention or management of a disease and enhancing their adoption by the community.**



FY2006 CTSA Funding Opportunities

- **RM-06-002: Institutional Clinical and Translational Science Award RFA**
- **RM-06-001: Planning Grant RFA for Institutional CTSA**
 - Allows more time to prepare a CTSA application
 - One time solicitation for one-year award
 - ~50 awards, \$150K direct costs; \$11.5 M total



CTSA Eligibility

- Domestic institutions, universities, academic health centers, or other organizations conducting clinical and translational research.
- A graduate school accredited to award higher degrees in clinical research must be included.
- Partnerships with independent and other research institutions are strongly encouraged.
- Institutions can only submit, or be part of, a single application.
- Applicants should show evidence of significant institutional commitment.



CTSA Eligibility

Domestic institutions, universities, academic health centers, or other organizations conducting clinical and translational research.

➤ **Excludes foreign institutions**



CTSA Eligibility

A graduate school accredited to award higher degrees in clinical research must be included.

- **The graduate school could be at an affiliate rather than the applicant institution. Prior awarding of higher degrees in clinical research (MS, PhD) is expected.**
- **By requiring a degree-granting academic program, NIH expects to create an environment that will foster the development of clinical and translational science as a distinct discipline**



CTSA Eligibility

The opportunities offered through a CTSA should be wide ranging. Participation by multiple schools (e.g., nursing, pharmacy, dentistry, engineering, to name a few) and partnerships with independent and other research institutions are strongly encouraged.

Institutions can only submit, or be part of, a single application.

The PI should have direct knowledge and hands-on involvement in the daily activities of the C/D/I - an established clinician scientist who reports directly to an official with broad trans-institutional authority.



CTSA Objectives: Speed Discoveries to Improved Patient Care

- **Develop a distinct discipline for clinical and translational science at institutions across the country**
- **Provide opportunities and resources for original research on novel methods**
- **Develop translational technologies and a knowledge base for the full spectrum of clinical and translational science**
- **Synergize partnerships with industry, foundations, and community physicians**
- **Train the interdisciplinary teams who will conduct the clinical and translational research of the future**



CTSA Funding

- Up to \$6 million in total costs per year in addition to combined current total costs of certain NIH awards
 - NCRR: K12, K30, M01 (GCRC)
 - Roadmap: T32 and K12
- Approximately \$30 M to support 4 –7 awards in FY 2006, in addition to amounts from existing awards
- Length of awards: 5 years
- Plan to expand to 60 awards, costing in aggregate up to \$500 M, by 2012
- Funded by NIH Roadmap for Medical Research and Existing NIH Programs



FY 2006 Timeline for Planning Grants and CTSAAs

- | | |
|----------------------------|-------------------------------------------------|
| -October 12, 2005: | Published RFAs (CTSA and Planning Grant) |
| -October 17, 2005: | CTSA Pre-Submission Meeting |
| -February 27, 2006: | Letters of Intent due |
| -March 27, 2006: | Applications due |
| -Summer 2006: | Review applications |
| -September 2006: | Fund Grants |



More Information



 **NIH Roadmap** ACCELERATING MEDICAL DISCOVERY TO IMPROVE HEALTH

- [Overview](#)
- [NIH Roadmap Initiatives](#)
- [Funding Opportunities](#)
- [Funded Research](#)
- [Roadmap Related Activities](#)
- [Public Meetings and Workshops](#)
- [Frequently Asked Questions](#)
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New Pathways to Discovery

- [Building Blocks, Biological Pathways, and Networks](#)
- [Molecular Libraries and Imaging](#)
- [Structural Biology](#)
- [Bioinformatics and Computational Biology](#)
- [Nanomedicine](#)

Research Teams of the Future

- [High-Risk Research](#)
 - [NIH Director's Pioneer Award](#)
- [Interdisciplinary Research](#)
- [Public-Private Partnerships](#)

Re-engineering the Clinical Research Enterprise

What's New

- **Press Release:** [NIH Launches Major Program to Transform Clinical and Translational Science](#)
- **RFA:** [Planning Grants for Institutional Clinical and Translational Science Awards](#)
- **RFA:** [Institutional Clinical and Translational Science Award](#)
- **Meeting:** [Interdisciplinary Research Centers Workshop](#)
- **Press Release:** [2005 NIH Director's Pioneer Award Recipients Announced](#)
- **Press Release:** [NIH Roadmap Continues to Move Forward on All Fronts](#)
- **Meeting Summary:** [BAA Roadmap](#)

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